

Appl. No. 09/845,036
Amdt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. - 20. (Cancelled)

21. (previously presented) A method of making a harvested mammary secretion product comprising an antibody specific for an antigen, the method comprising:
hyperimmunizing a farm-animal for the antigen (i) via a mucosal passage of the farm-animal, the mucosal passage selected from the group consisting of an intravaginal passage, an intrarectal passage, and an intranasal passage of the animal, or (ii) via inhalation through an airway of the farm animal;
administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal; and
harvesting the mammary secretion product from the farm-animal.

22. (previously presented) The method of claim 21, wherein the hyperimmunizing step comprises administering the antigen via inhalation through an airway of the farm-animal.

23. (previously presented) The method of claim 22, wherein the hyperimmunizing step comprises administering the antigen intranasally to the farm-animal.

24. (previously presented) The method of claim 21, wherein the mammary secretion product is milk.

25. (previously presented) The method of claim 21, wherein the antibody is an IgA antibody.

Appl. No. 09/845,036
Amdt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

26. (previously presented) The method of claim 21, further comprising boosting an immune response to the antigen in the farm-animal.

27. (previously presented) The method of claim 26, wherein the boosting step comprises administering the antigen to an airway, a mammary gland, and/or a supramammary lymph node of the farm-animal.

28. (previously presented) A method of making an antibody composition comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen (i) via a mucosal passage of the farm-animal, the mucosal passage selected from the group consisting of an intravaginal passage, an intrarectal passage, and an intranasal passage of the animal, or (ii) via inhalation through an airway of the farm animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and
deriving the antibody composition from the harvested mammary secretion product.

29. (previously presented) A method of making an antigen-specific antibody, the method comprising:

hyperimmunizing a farm-animal for the antigen (i) via a mucosal passage of the farm-animal, the mucosal passage selected from the group consisting of an intravaginal passage, an intrarectal passage, and an intranasal passage of the animal, or (ii) via inhalation through an airway of the farm animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting a mammary secretion product from the farm-animal; and

Appl. No. 09/845,036
Amdt, fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

deriving the antigen-specific antibody from the harvested mammary secretion product.

30. (previously presented) A method of making a medicament comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen (i) via a mucosal passage of the farm-animal, the mucosal passage selected from the group consisting of an intravaginal passage, an intrarectal passage, and an intranasal passage of the animal, or (ii) via inhalation through an airway of the farm animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and preparing the medicament from the secretion product.

31. (previously presented) A method of making a food product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen (i) via a mucosal passage of the farm-animal, the mucosal passage selected from the group consisting of an intravaginal passage, an intrarectal passage, and an intranasal passage of the animal, or (ii) via inhalation through an airway of the farm animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and preparing the food product from the secretion product.

32. (Cancelled)

33. (previously presented) The method of claim 21, wherein the antigen is administered at least once in the supramammary lymph node.

Appl. No. 09/845,036
Amdt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

34. (previously presented) The method of claim 21, wherein the antigen is administered at least twice in the supramammary lymph node.
35. (previously presented) The method of claim 21, wherein the farm-animal is a cow or a goat.
36. (previously presented) The method of claim 21, wherein the hyperimmunizing step further comprises administering an adjuvant to the farm-animal.
37. (previously presented) The method of claim 36, wherein the adjuvant is toxin B of *Clostridium difficile*.
38. (previously presented) The method of claim 21, wherein the antigen is derived from a culture of *Clostridium difficile*.
39. (previously presented) The method of claim 38, wherein the antigen is a protein from a *Clostridium difficile* (VPI10463) cell.
40. (previously presented) The method of claim 38, wherein the antigen is a *Clostridium difficile* spore.
41. (previously presented) The method of claim 38, wherein the antigen comprises *Clostridium difficile* Toxin A.
42. (previously presented) The method of claim 38, wherein the antigen comprises *Clostridium difficile* Toxin B.
43. (previously presented) The method of claim 38, wherein the antibody is specific for a protein of *Clostridium difficile*.
44. (previously presented) The method of claim 38, wherein the antibody is specific for a *Clostridium difficile* spore.

Appl. No. 09/845,036
Amndt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

45. (previously presented) The method of claim 21, wherein the farm-animal is a lactating farm-animal.

46. (Canceled)

47. (previously presented) The method of claim 21, wherein the airway administration is achieved in the form of aerosols.

48. (previously presented) The method of claim 21, wherein the hyperimmunizing step comprises at least two airway administrations of the antigen.

49. (previously presented) The method of claim 21, wherein the hyperimmunizing step comprises at least four airway administrations of the antigen.

50. (previously presented) The method of claim 21, wherein the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal about 6 weeks following the hyperimmunizing step.

51. (previously presented) The method of claim 21, wherein the harvested mammary secretion product has an IgA titer of at least 1000 units/ml.

52. (previously presented) The method of claim 21, wherein the harvested mammary secretion product has an IgA titer of at least 1000 units/ml and is harvested up to about 10 weeks after the antigen is administered to the mammary gland and/or the supramammary lymph node of the farm-animal.

53. (previously presented) The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of at least 100 units/ml.

54. (previously presented) The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of at least 100 units/ml and is harvested up to about

Appl. No. 09/845,036
Amdt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

8 weeks after the antigen is administered to the mammary gland and/or the supramammary lymph node of the farm-animal.

55. (previously presented) The method of claim 21, wherein the hyperimmunizing step further comprises administering the antigen intramuscularly to the farm animal.

56. (previously presented) The method of claim 21, wherein the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal about 3 weeks following the hyperimmunizing step.

57. (previously presented) The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of about 130 units/ml to about 430 units/ml.

58. (previously presented) The method of claim 21, wherein a second hyperimmunization step is performed after the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal.

59. (previously presented) The method of claim 58, wherein the antigen is administered a second time to the mammary gland and/or supramammary lymph node of the farm-animal following the second hyperimmunization step.

60. (previously presented) The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration has an IgG titer of at least 400 units/ml.

61. (previously presented) The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration has an IgA titer of at least 3500 units/ml.

Appl. No. 09/845,036
Amndt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

62. (previously presented) The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration does not have a strong quarter specificity for IgA titer.

63. (currently amended) The method of claim 24, wherein the milk from the farm-animal comprises at least 0.5 $\mu\text{g} [[\text{g}]] / \text{ml}$ of antibody specific for the antigen.

64. (currently amended) The method of claim 24, wherein the milk from the farm-animal comprises at least 15 $\mu\text{g} [[\text{g}]] / \text{ml}$ of antibody specific for the antigen.

65. (currently amended) The method of claim 24, wherein the milk from the farm-animal comprises at least 50 $\mu\text{g} [[\text{g}]] / \text{ml}$ of antibody specific for the antigen.

66. (previously presented) The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 50 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

67. (previously presented) The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 100 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

68. (previously presented) The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 200 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

69. (previously presented) The method of claim 62, wherein the antibody specific for the antigen is an IgA antibody.

Appl. No. 09/845,036
Amdt. fax-filed on January 12, 2005
Amendment under 37 CFR 1.116
Expedited Procedure - Examining Group 1644

PATENT

70. (previously presented) The method of claim 63, wherein the antibody specific for the antigen is an IgA antibody.

71. (previously presented) The method of claim 64, wherein the antibody specific for the antigen is an IgA antibody.

72. (previously presented) The method of claim 65, wherein the antibody specific for the antigen is an IgA antibody.

73. (previously presented) The method of claim 66, wherein the antibody specific for the antigen is an IgA antibody.

74. (previously presented) The method of claim 67, wherein the antibody specific for the antigen is an IgA antibody.

75. (canceled)

76. (previously presented) The method of claim 21, further comprising removing fat and casein from the harvested mammary secretion product.

77. (previously presented) The method of claim 28, further comprising removing fat and casein from the harvested mammary secretion product.

78. (previously presented) The method of claim 29, further comprising removing fat and casein from the harvested mammary secretion product.

79. (previously presented) The method of claim 30, further comprising removing fat and casein from the harvested mammary secretion product.

80. (previously presented) The method of claim 31, further comprising removing fat and casein from the harvested mammary secretion product.